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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/552,461	04/18/2000	William J. Kokolus	WKP:101(b) US	2322

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06/05/2002

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EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 06/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/552,461

Applicant(s)

KOKOLUS, WILLIAM J.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 12 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claims Rejections-35 USC 112***

Claims 12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "a diagnostic method comprising the step..." in claims 12 and 19 fails to point out exactly what is being diagnosed. Is this to diagnose prostate cancer in general, specific prostate cancer associated genes, serum PSA, complexed PSA, or some other type of cancer. This is unclear and needs to be clarified in the claim language.

#### ***Claims Rejections-35 USC 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopp (US 4,554,101) and further in view Hopp (Methods in Enzymology (1981) vol. 178, pp.571-583). Hopp (US 4,554,101) teaches a system for determining the portion of a protein antigen that is responsible for the antigenicity of the protein and methods for preparing and using synthetic antigens (column 1, lines 36-55). As required by claims 12 and 19, Hopp describes the method of assigning relative hydrophilicity values in accordance with a generated table of values for each amino acid. Using this method, hydrophilicity for each precise point can be ranked and graphically determined (curve) in order to determine the sequence of amino acids recognized by and bound by an antibody with immunological specificity (termed the "H" epitope) (column 3, lines 1-6). Furthermore, using this technique, mono-specific antibodies can be generated that can serve as a source for diagnostic serological testing (column 124, lines 62-68 and column 15, lines 1-3). Hopp does not specifically describe his method of hydrophilicity plotting and generation, however this process is more clearly defined and described in the 1981 Hopps paper. For example the hydrophilicity analysis method of Hopps and Woods is described as the first to combine moving-average plotting procedures with a complete scale of hydrophilicity values. The scale was derived from the hydrophobicity values of Nozaki and Tanford and extended to provide a complete set of values including those for hydrophilic amino acids (page 574, paragraph 2). The H-epitope in this invention is defined by at least six amino acids corresponding to the greatest average local hydrophilicity of the antigen. It would have been

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prima facie obvious to one of ordinary skill in the art to combine the teachings of US 4,554,101 with the specific disclosed methods of hydrophobicity/hydrophilicity plotting in the Hopps 1981 paper in order to identify and develop the specific epitope determinants of the instant invention. It is well known in the art that this method of Hopps and Woods can be used to predict epitopes for generation of peptide antibodies. Furthermore, there is a software program designed from this specific method that is available for to design these very antibodies (HYDRO program) (page 578, paragraph 2).

No claim is allowed.

### *Inquiries*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3419, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

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June 3, 2002

Lori A. Clow, Ph.D.  
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*Lori A. Clow*



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